APR - 6 2012

5. 510(k) Summary

Date Prepared:

March 13, 2012

Submitter's Information:

FUJIFILM Medical Systems U.S.A., Inc.
419 West Avenue
Stamford, Connecticut 06902

Telephone: (203) 602-3774
Facsimile: (203) 363-3813
Contact: Debra A. Peacock

Device Trade Name:

Synapse 3D Base Tools

Device Common Name:

Medical Image Processing and Analysis Software

Regulation Number:

21 CFR 892.2050

Device Classification:

Class II

Device Classification Name

Picture Archiving Communication System (PACS)

Panel:

Radiology

Product Code:

90-LLZ

Date Received:

TBD

Decision Date:

TBD

Decision:

TBD

Predicate Devices:

- READY View, (K110573), General Electric Medical Systems
- Advantage Windows 3D Option and DentaScan Option (K923077), General Electric Medical Systems
- Synapse 3D Basic Tools (K101662), FUJIFILM Medical Systems, U.S.A., Inc.

Description of the Device

The SYNAPSE 3D Base Tools software is medical application software running on Windows Server 2008 installed on commercial general-purpose Windows-compatible computers. SYNAPSE 3D Basic Tools software is connected through DICOM standard to other medical devices such as CT, MR, CR, US, NM, PT, XA, etc. and to PACS systems storing data generated by these medical devices. Image data obtained from these devices are used for display, image processing, analysis, etc. SYNAPSE 3D Base Tools cannot be used to interpret Mammography images.

SYNAPSE 3D Base Tools can be integrated with Synapse Workstation (cleared by CDRH via K051553 on 07/07/2005) and can be used as a part of a SYNAPSE system.

SYNAPSE 3 D Base Tools Version 3.0 expands upon the applications listed in Synapse 3D Basic Tools, #K101662 with the addition of the below new applications. In addition, new and improved algorithms are listed in Section 11.1.4.

- Slicer

  Slicer creates multiple cross-sectional images along an object such as spine with MPR processing using CT or MR data. The user can adjust the location of reference lines manually to obtain desired slices.

- Combination

  Combination can concatenate separated series data acquired for a single body into one single series.

- Dental MPR

Dental MPR creates a cross-sectional image along the specified line on teeth with MPR, including CPR, processing using head CT data.

- ADC Viewer

ADC Viewer accepts MR diffused weighted images, calculates ADC (Apparent Diffusion Coefficients) and EADC (Exponential ADC) values for each pixel using the known equations, and displays color mapped ADC and EADC images.

Indications for Use:

Synapse 3D Base Tools is medical imaging software that is intended to provide trained medical professionals with tools to aid them in reading, interpreting, reporting, and treatment planning. Synapse 3D Base Tools accepts DICOM compliant medical images acquired from a variety of imaging devices including, CT, MR, CR, US, NM, PT, and XA, etc.

This product is not intended for use with or for the primary diagnostic interpretation of Mammography images.

Synapse 3D Base Tools provides several levels of tools to the user:

Basic imaging tools for general images, including 2D viewing, volume rendering and 3D volume viewing, orthogonal / oblique / curved Multi-Planar Reconstructions (MPR), Maximum (MIP), Average (RaySum) and Minimum (MinIP) Intensity Projection, 4D volume viewing, image fusion, image subtraction, surface rendering, sector and rectangular shape MPR image viewing, MPR for dental images, creating and displaying multiple MPR images along an object, time-density distribution, basic image processing, CINE, measurements, annotations, reporting, printing, storing, distribution, and general image management and administration tools, etc.

- Tools for regional segmentation of anatomical structures within the image data, path definition through vascular and other tubular structures, and boundary detection.
- Image viewing tools for modality specific images, including CT PET fusion and ADC image viewing for MR studies.

Technological Characteristics

Synapse 3D Base Tools V3.0 introduces no new safety or efficacy issues other than those already indentified with the predicate devices. The results of the Hazard Analysis combined with the appropriate preventive measures taken indicate that the device is of moderate concern as per the May 11, 2005 issue of the "Guidance for the Content of Premarket Submission for Software Contained in Medical Devices."

Testing

Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the proposed device.

Testing involved system level functionality test, segmentation accuracy test, measurement accuracy test, interfacing test, usability test, serviceability test, labeling test, as well as the test for risk mitigation method analyzed and implemented in the risk management process, in the same manner as our previously-cleared predicate device.

Pass/Fail criteria were based on the requirements and intended use of the product. Test results showed that all tests successfully passed.

Conclusion

This 510(k) premarket notification submission has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health. We conclude the subject device to be as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Debbie Peacock
Regulatory Affairs Manager
FUJIFILM Medical Systems, USA Inc.
419 West Avenue
STAMFORD CT 06902

APR - 6 2012

Re: K120361
Trade/Device Name: Synapse 3D Base Tools
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 14, 2012
Received: March 14, 2012

Dear Ms. Peacock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K120361

Indications for Use

510(k) Number (if known):

Device Name: Synapse 3D Base Tools

Indications for Use:

Synapse 3D Base Tools is medical imaging software that is intended to provide trained medical professionals with tools to aid them in reading, interpreting, reporting, and treatment planning. Synapse 3D Base Tools accepts DICOM compliant medical images acquired from a variety of imaging devices including, CT, MR, CR, US, NM, PT, and XA, etc.
This product is not intended for use with or for the primary diagnostic interpretation of Mammography images.
Synapse 3D Base Tools provides several levels of tools to the user:

- Basic imaging tools for general images, including 2D viewing, volume rendering and 3D volume viewing, orthogonal / oblique / curved Multi-Planar Reconstructions (MPR), Maximum (MIP), Average (RaySum) and Minimum (MinIP) Intensity Projection, 4D volume viewing, image fusion, image subtraction, surface rendering, sector and rectangular shape MPR image viewing, MPR for dental images, creating and displaying multiple MPR images along an object, time-density distribution, basic image processing, CINE, measurements, annotations, reporting, printing, storing, distribution, and general image management and administration tools, etc.
- Tools for regional segmentation of anatomical structures within the image data, path definition through vascular and other tubular structures, and boundary detection.
- Image viewing tools for modality specific images, including CT PET fusion and ADC image viewing for MR studies.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K120361